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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,747	11/21/2005	Toru Nishibayashi	Q91609	2298
23373 7590 09/15/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER SZNAIDMAN, MARCOS L	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 09/15/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/557,747

**Applicant(s)**

NISHIBAYASHI ET AL.

**Examiner**

MARCOS SZNAIDMAN

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 24, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This is office action in response to applicant's request for continued examination filed on June 30, 2009.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

#### ***Status of Claims***

Amendment of claims 1, 24 and 26, and cancellation of claims 2-23 and 25 is acknowledged.

Claims 1, 24 and 26-27 are currently pending and are the subject of this office action.

Claim 24 was withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 31, 2008.

Claims 1 and 26-27 are presently under examination.

Even though Applicant has amended claim 1 by incorporating a non-elected invention, the claim is being examined for the elected invention only.

***Priority***

The present application is a 371 of PCT/JP04/07436 filed on 05/252004.

***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103 (Maintained rejection)***

Claims 1, and 26-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et. al. (US 5,376,686, cited by applicant, cited in prior office action).

The reasons for this rejection have been provided in the previous office action dated March 4, 2009, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that the restriction requirement filed on 03/07/08 is improper, and as such the incorporation of subject matter originally filed in claim 3 (now cancelled) which corresponds to a non-elected invention s, should be entered.

Examiner's response: Applicant is referred to the response of the office action mailed 07/22/08, the text of which is incorporated by reference herein.

The following arguments are just to clarify this issue: a composition comprising olanexidine and an excipient, such as polyoxyethylene higher alkyl ether can not be a special technical feature because it is already known in the prior art. See for example Ishikawa et. al. used for the 103 rejection. Ishikawa teaches a composition of olanexidine with a polyoxyethylene-based nonionic phenyl ether (see columns 23 and 24: Prescriptions 1 and 2). As such the Ishikawa reference makes the combinations of the instant application obvious and as such they can not be special technical features.

Applicant presents the same arguments as before regarding the 103 rejection.

Examiner's response: Applicant is referred to the response provided in the office action mailed on 03/04/2009, the text of which is incorporated by reference herein.

Applicant's new arguments are: Additionally, Applicants submit that the present invention provides unexpectedly superior results. For example, the polyoxyethylene higher alkyl ether of the present invention (Examples 3 to 5) exhibits almost the same excellent anti-bactericidal activity as the polyoxyethylene alkylphenyl ether of the

present invention (see Example 2) and the polyoxyethylene alkylphenyl ether of the present invention exhibits bactericidal activity remarkably superior to that of the "polyoxyethylene phenyl ether" of Ishikawa. Thus, from the data provided in the present specification, it is clear that the polyoxyethylene higher alkyl ether of the present invention has bactericidal activity superior to that of the polyoxyethylene phenyl ether of Ishikawa. For this additional reason the present invention is patentable over the prior art.

Examiner's response: Applicant's arguments are not supported by the data from the specification. The specification provides examples of combinations of olaxenidine with polyoxyethylene alkylphenyl ether (Example 2) and polyoxyethylene higher alkyl ether (Examples 3, 4 and 5) (see pages 26-27), and although the specification provides bactericidal activity of these compositions against a variety of strands (see Table 2), there is no comparative data with the Ishikawa's composition.

MPEP 716.01(c) states: Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with

those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument." ). See also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991) .

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

### ***Conclusion***

No claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
August 18, 2009

/Frederick Krass/  
Supervisory Patent Examiner, Art  
Unit 1612